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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,788	09/17/2003	Yeung Siu Yu	LIFE-004DIV	9001

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EXAMINER	
FORMAN, BETTY J	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 02/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,788	YU ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 21-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 21-26 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 21-23 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bamdad (U.S. Patent No. 6,306,584, filed 10 April 1997) in view of Backhaus et al (U.S. Patent No. 5,869,001, issued 9 February 1999).

Regarding Claim 21, Bamdad teaches a kit (Column 5, lines 12-20) comprising an electrochemical test strip comprising: a reaction zone defined by opposing working and reference electrodes separated by a spacer layer (e.g. Fig. 15-17 and Column 23, line 3-Column 24, line 33) wherein at least one of the electrodes has a surface modified with a homogenous surface modification layer made up of self assembling molecules (SAM) having a first sulfhydryl end group (Column 11, line 6-Column 12, line 67); and a redox reagent system in said reaction zone, said redox reagent system comprising at least one enzyme and a mediator (Column 24, line 43-Column 25, line 30 and Example 17, Column 44, line 60-Column 45, line 30) and a means for obtaining a sample (e.g. inlet #93) and an analyte standard (e.g. positive and negative controls, Column 32, lines 14-17)1. Bamdad teaches the SAM comprises a functional group which adheres to the surface (e.g. sulfhydryl, Column 10, lines 30-37; Column 12, lines 3-45; and Column 15, line 37-Column 16, line 42) and a minor component for biomolecule attachment (Column 16, lines 12-15) but Bamdad does not teach the biomolecule is attached via a SAM having sulfonate end group. However, Backhaus et al teach a preferred method for modifying an electrode surface to receive a reagent comprises modifying the electrode surface

with an alkyl linker group comprising a first sulfhydryl end and a second sulfonate end (Column 7, lines 45-53). Specifically, Backhaus et al teach that alkyl chains terminating at one end with a sulfhydryl group bind especially well to gold electrode surfaces and when terminating at the other end with a sulfonate group to provide a hydrophilic surface as preferred for receiving a aqueous reagents (Column 7, lines 37-40 and 45-49). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify SAM functional groups taught by Bamdad by attaching a sulfonate group on the SAM thereby providing a hydrophilic surface for attaching and/or receiving aqueous reagents as taught by Backhaus et al (Column 7, lines 38-40). One of ordinary skill would have been motivated to apply the sulfonate group to the SAM of Bamdad to thereby increase the hydrophilic properties of the surface for the expected benefit increasing interaction with an aqueous sample e.g. body fluid samples as suggested by Backhaus (Column 7, lines 39-40).

Regarding Claim 22, Bamdad teaches the kit wherein the analyte is glucose i.e. glucose test meter (Column 23, lines 20-60).

Regarding Claim 23, Bamdad teaches the kit wherein the sample is blood (e.g. Column 25, line 67)

Regarding Claim 25, Bamdad teaches the kit comprising a test strip as described above and further teaches test strip is present in an automated instrument designed to work with test strips (Column 23, lines 20-60) and Backhaus et al teach the similar test strip is present in an automated instrument which is designed to work with test strips e.g. spectrophotometer (Column 6, lines 3-23).

Regarding Claim 26, Bamdad teaches the test strip as described above wherein the test strip is present in an automated instrument designed to work with test strips (Column 23, lines 20-60) and Backhaus et al teach the similar test strip is present in an automated instrument which is designed to work with test strips e.g. spectrophotometer (Column 6, lines 3-23).

3. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bamdad (U.S. Patent No. 6,306,584, filed 10 April 1997) in view of Backhaus et al (U.S. Patent No. 5,869,001, issued 9 February 1999) as applied to Claim 21 above and further in view of Blackman (U.S. Patent No. 4,813,538 issued 21 March 1989).

Regarding Claim 24, Bamdad and Backhaus et al disclose the kit of Claim 21 as described above wherein the sample is blood (Column 25, line 67) and the analyte is glucose (Column 23, lines 20-60) but they do not teach the kit comprising a lance for obtaining the blood sample. However, kits comprising a lance for obtaining blood samples were well known in the art at the time the claimed invention was made as taught by Blackman who teaches the lance provides a reusable means of obtaining blood samples (Abstract, Column 5, lines 6-9 and Claims 13-15). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the kit of Bamdad and Backhaus et al by including the lance of Blackman. One of ordinary skill in the art would have been motivated to do so based on the economy and convenience of reusable components as taught by Blackman (Column 2, lines 14-17).

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claim 26 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,716,577 in view of Bamdad (U.S. Patent No. 6,306,584, filed 10 April 1997) or Backhaus et al (U.S. Patent No. 5,869,001, issued 9 February 1999). Instant Claim 26 and patent Claim 1 are both drawn to test strips. The claims differ in that the test strip of instant Claim 26 is within a "system" comprising an "automated instrument". Test strips within systems comprising automated instruments were well known in the art at the time the claimed invention was made as taught by both Bamdad and Backhaus. Bamdad teaches the test strip as described above wherein the test strip is present in an automated instrument designed to work with test strips (Columns 23-24, e.g. network analyzer, Column 24, lines 43-56) and Backhaus et al teach the similar test strip is present in an automated instrument which is designed to work with test strips e.g. spectrophotometer (Column 6, lines 3-23). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the automated instrument of Bamdad and Backhaus to the patent test strip for the obvious benefit of networked analysis of reaction on the test strip as taught by Bamdad (Column 24, lines 43-56).

Furthermore, the courts have stated that broadly providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art (see: *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958)) (see MPEP 2144.04 III). Therefore, the combining the patent test strip with an automated instrument would not distinguish the combination over the patent test strip.

6. Claims 21, and 26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-23 of U.S. Patent No. 6,558,528 in view of Backhaus et al (U.S. Patent No. 5,869,001, issued 9 February 1999).

The instant and patent claims are drawn to kits and systems comprising a very similar electrode test strips. The claims differ in that the instantly claimed test strips have a surface modified with a surface modification layer. However modification of electrode surfaces as instantly claimed was well known in the art at the time the claimed invention was made. Specifically, Backhaus et al teach that alkyl chains terminating at one end with a sulfhydryl group bind especially well to gold electrode surfaces and when terminating at the other end with a sulfonate group to provide a hydrophilic surface as preferred for receiving a aqueous reagents (Column 7, lines 37-40 and 45-49). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the patent electrodes by surface modification with a SAM bearing sulfonate group to thereby provide a hydrophilic surface for attaching and/or receiving aqueous reagents as taught by Backhaus et al (Column 7, lines 38-40). One of ordinary skill would have been motivated to apply the SAM-bearing sulfonate group to the patent test strip to thereby increase the hydrophilic properties of the surface for the expected benefit increasing interaction with an aqueous sample e.g. body fluid samples as suggested by Backhaus (Column 7, lines 39-40) and for the preferred use of the patent test strip.

7. Claims 21-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-24 of U.S. Patent No. 6,855,243 in view of in view of Backhaus et al (U.S. Patent No. 5,869,001, issued 9 February 1999).

The instant and patent claims are drawn to kits and systems comprising a very similar electrode test strips. The claims differ in that the instantly claimed test strips have a surface modified with a surface modification layer. However, modification of electrode surfaces as instantly claimed was well known in the art at the time the claimed invention was made. Specifically, Backhaus et al teach that alkyl chains terminating at one end with a sulfhydryl group bind especially well to gold electrode surfaces and when terminating at the other end with a sulfonate group to provide a hydrophilic surface as preferred for receiving a aqueous reagents (Column 7, lines 37-40 and 45-49). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the patent electrodes by surface modification with a SAM bearing sulfonate group to thereby provide a hydrophilic surface for attaching and/or receiving aqueous reagents as taught by Backhaus et al (Column 7, lines 38-40). One of ordinary skill would have been motivated to apply the SAM-bearing sulfonate group to the patent test strip to thereby increase the hydrophilic properties of the surface for the expected benefit increasing interaction with an aqueous sample e.g. body fluid samples as suggested by Backhaus (Column 7, lines 39-40) and for the preferred use of the patent test strip.

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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Art Unit: 1634
February 1, 2006